

**AMENDMENT UNDER 37 C.F.R. § 1.111  
U.S. Appln. No. 10/581,717 (Q95277)**

**REMARKS**

**Status of Claims and Amendment**

Claims 1-4, 7, 8, 15, and 16 have been amended. Claim 6 has been canceled. Claims 1-5 and 7-28 are all the claims pending in this application. Claims 1-6 and 16-18 are all the pending claims being examined in the present application. Claims 7-15 and 19-28 are withdrawn as being directed to a non-elected invention. Claims 1-6 and 16-18 are rejected.

Claim 1 has been amended to incorporate the limitations of claim 6. Support for the amendment to claim 1 may be found throughout the specification, for example, at page 13, paragraph [0031], and original claim 6.

Claim 2 has been amended to delete “endogluconase activity.”

Claims 3 and 4 have been amended to delete “endogluconase activity and the amino acid sequence of SEQ ID NO: 1 at the N-terminus thereof.”

Claims 7, 15, and 16 have been amended to correct the claim dependencies in order to be consistent with the amendments to claim 1.

Claim 8 has been amended to be dependent on claim 1. Support for the amendment to claim 8 may be found throughout the specification, for example, in the Sequence Listing.

No new matter is added.

**Request for Rejoinder**

Applicants note that pursuant to M.P.E.P. § 821.04(a) (entitled “Rejoinder Between Product Inventions; Rejoinder Between Process Inventions”), M.P.E.P. § 821.04 (b) (entitled “Rejoinder of Process Requiring An Allowable Product”), and 37 C.F.R. § 1.104, where a product claim is subsequently found allowable, withdrawn claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined. Applicants

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respectfully request rejoinder of claims 7-14 pursuant to M.P.E.P. § 821.04(a), and claims 15 and 19-28 pursuant to M.P.E.P. § 821.04(b).

**Response To Rejections Under 35 U.S.C. § 112**

**A. Enablement Rejection**

Claim 6 remains rejected under 35 U.S.C. 112, first paragraph, for lack of enablement for the same reasons of record.

In addition, the Office Action appears to assert that the methods known in the art only enable methods for searching and screening an amino acid sequence having at least 85% homology to SEQ ID NO:3 and having endoglucanase activity. The Office Action cites Chica *et al.* (Curr Opin Biotechnol. 2005 Aug;16(4):378-84) for the proposition that enzyme modification requires an understanding of the structure/function relationship.

In an attempt to rectify the rejection the Office Action cites Sen *et al.* (Appl. Biochem. Biotechnol., 2007 Dec;143(3):212-23) for teaching *in vitro* recombination techniques. The Office Action appears to assert that although there are general teachings that enable searching and screening, such searching and screening is insufficient guidance for making a protein having at least 85% homology and having endoglucanase activity.

Thus, the Office Action appears to assert that because of the broad scope encompassed by the claims, one of ordinary skill in the art would require undue experimentation to make and use the claimed invention.

In response, Applicants respectfully note that the Office Action has disregarded Applicants' previous arguments, and taken a position that is inconsistent with the Board of Appeals and Interferences' (BPAI) interpretation of the enablement statute. As previously argued, the BPAI has found that a claimed genus of sequences with 80% similarity to an

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identified sequence with a maintained functionality is enabled, because although the amount of experimentation to practice the full scope of the invention may be extensive, it would have been routine because the techniques are well known to those of ordinary skill in the art. *Ex parte Kubin* (BPAI 2007) (noting that the level of skill in the molecular biology art is high and the methods for making the claimed sequences and screening for activity were known in the art and described in the specification so that experimentation to produce other sequences within the scope of the claims is well within the skill of those in the art). Thus, the BPAI has recognized that mere routine experimentation is required to enable the full scope of an Applicants' claims reciting nucleic acids encoding proteins having at least 80% identity to the disclosed amino acid sequence claimed.

In the present case, the specification discloses the claimed amino acid sequence of SEQ ID NO:3, how to make variants of SEQ ID NO:3 (page 12, paragraph [0027] to page 14, paragraph [0033], page 16, paragraph [0038] to page 18, paragraph [0047]), calculate the percent identity between SEQ ID NO:3 and the variant sequence (page 14, paragraph [0034] to paragraph [0036], Figures 1 and 2), and test the variant sequence for endoglucanase activity (page 10, paragraph [0022], page 16, paragraph [0039]), as well as Examples on how to make the claimed variant sequence. Accordingly, similar to *Kubin*, the methods disclosed in the present specification are common in molecular biology applications, as minor changes in gene sequences can still have the same function as the unaltered sequence.

Furthermore, as previously argued, it would be within common technical practice for one skilled in the art to perform a homology search or alignment to determine the degree of similarity between the sequences disclosed, and to surmise from the homology search or alignment, the regions of conserved amino acids that are important for function without undue experimentation.

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As disclosed at the bottom of page 13 of the present specification, one skilled in the art would understand and surmise based on common technical knowledge and common sense, e.g., determination of homology in the amino acid sequence based on a FASTA3 calculation or BLAST search algorithm, and the disclosure in the specification, how to make and use the claimed isolated protein comprising an amino acid sequence having at least 85% identity to SEQ ID NO:3. In fact, the references cited by the Examiner are fully supportive of Applicants' position that because the methods are known and available to those skilled in the art, the claimed invention is enabled.<sup>1</sup>

However, and solely to advance prosecution of the present application, claim 6 has been canceled. Accordingly, the rejection with regard to claim 6 is rendered moot.

Withdrawal of the rejection under 35 U.S.C. 112, first paragraph, is respectfully requested.

**B. Written Description Rejection**

Claims 1-5 and 16-18 are rejected under 35 U.S.C. 112, first paragraph, for alleged lack of written description.

Specifically, the Office Action asserts that the claims encompass a broad genus of proteins from any amino acid sequence belonging to the genus *Staphylotrichum*. Further, the Office Action appears to assert that even if the claims recite a homologous protein, for instance, comprising an amino acid sequence having at least 85% homology to SEQ ID NO:3 and having

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<sup>1</sup> Sen *et al.* as cited by the Office Action teach that the engineering of enzymes with altered activity, specificity and stability, using directed evolutionarily techniques is now well established. Emphasis added. (See Abstract). Accordingly, the Office is respectfully requested to note that "a patent need not teach, and preferably omits, what is well known in the art." (See *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986)).

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endoglucanase activity, there is insufficient disclosure in the specification to teach which the 15% of the structure is involved in retaining the endoglucanase activity.

In response, Applicants note that the presently claimed isolated protein is fully described in the specification, for example, at page 12, paragraph [0030] to paragraph [0036] of page 15 and Figures 1 and 2. Further, the structures associated with the endoglucanase activity is recognized in the art to be associated with the catalytic domain (amino acids at positions 1 to 207 of SEQ ID NO:3), linker region (amino acids at positions 208 to 258 of SEQ ID NO:3), and cellulose-binding domain (amino acids at positions 259 to 295 of SEQ ID NO:3). (See paragraph [0035]-[0036] of the specification). Thus, the specification fully discloses the presently claimed isolated protein as well as the structure involved in retaining the endoglucanase activity.

However, and solely to advance prosecution of the present application, claim 1 has been amended to recite the limitations of claim 6, which is not rejected for lack of written description.

Withdrawal of the rejection under 35 U.S.C. 112, first paragraph, is respectfully requested.

**Response To Rejections Under 35 U.S.C. § 102(b)**

Claims 1, 5, 17, and 18 remain rejected under 35 U.S.C. 102(b) as being anticipated by Rasmussen *et al.* (WO 91/17243) for the same reasons of record.

In addition, the Office Action asserts that the arguments filed July 30, 2006 are not persuasive, because without any specific recitation of the amino acid sequences and structures of the claimed protein having endoglucanase activity, the claims are deemed to encompass any endoglucanase, and thus are anticipated by the teachings Rasmussen.

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In response, and as previously argued, Rasmussen does not explicitly or inherently disclose the presently claimed isolated protein.

Withdrawal of the rejection under 35 U.S.C. 102(b) is respectfully requested.

**Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The U.S. Patent and Trademark Office is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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